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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/582,779      | 07/03/2000  | MARKUS POMPEJUS      | 48715               | 2744             |

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KEIL & WEINKAUF  
1350 CONNECTICUT AVENUE, N.W.  
WASHINGTON, DC 20036

EXAMINER

GUZO, DAVID

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1636

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DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/582,779

Applicant(s)

POMPEJUS ET AL.

Examiner

David Guzo

Art Unit

1636

**Period for Reply**  
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002 and 08 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1636

### Detailed Action

A corrected filing receipt was mailed 1/23/03.

The substitute Abstract filed 12/23/02 is acceptable.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants disclose an orotidine-5'-phosphate decarboxylase (OMP-DC) gene isolated from *A. gossypii* (SEQ ID NO:1). Applicants claim polypeptides encoded by this gene or homologs of SEQ ID NO:1, gene constructs comprising SEQ ID NO:1 or its homologs, homologs having 80% homology with SEQ ID NO:1, microorganisms containing said gene or a homolog and methods of inserting DNA into cells or selecting cells comprising use of SEQ ID NO:1 or its homologs.

This rejection is maintained for reasons of record in the previous Office Action (Paper #20) and for reasons outlined below. Applicants traverse this rejection by asserting that the rejection relating to homologs of SEQ ID NO:1 should be limited only to claims 16-17 because none of the other claims recite this limitation.

Art Unit: 1636

Applicant's arguments filed 12/23/02 have been fully considered but they are not persuasive. It is noted that claims 3-17 recite homologs of SEQ ID NO:1 and hence the rejection is still applicable to these claims.

Applicants assert that one of skill in the art knows that sequences such as SEQ ID N:1 can be modified by genetic engineering without affecting the biological activity of the corresponding protein.

In response, the examiner notes that this argument does not address where in the nucleic acid sequence these changes can be made without affecting the biological activity of the resulting protein. It is noted that applicants are claiming a genus of sequences encoding OMP-DC proteins with no correlation between the structure of the OMP-DC sequence and its function. Essentially, applicants appear to be asserting that they do not need to know the functional motifs of the OMP-DC gene because one of skill in the art could generate other members of the genus essentially by practicing trial and error experimentation to make changes randomly in the gene sequence and screen for sequences that maintain biological activity. This argument is not persuasive because without a correlation between structure and function, the structure of other members of the genus which could be obtained by genetic engineering is unknown to applicant. It must therefore be concluded that the one species disclosed by applicant (SEQ ID NO:1) is not a representative number of species and would be insufficient to convince the skilled artisan that applicant was **in possession** of the claimed genus.

Art Unit: 1636

Applicants assert that they are not claiming the nucleic acid solely by function, but instead have disclosed its structure (SEQ ID NO:1). Therefore, applicants assert that 80% homologs are described, even if partially, by the structure of SEQ ID NO:1.

In response, the examiner notes that applicants have disclosed one member of the claimed genus without a correlation between the structure of the sequence and its function. While the disclosure of the one species of the genus provides relevant identifying characteristics for that species (SEQ ID NO:1), the absence of a correlation between the structure of the disclosed sequence and its function means that applicants have provided no relevant identifying characteristics for the functional homologs recited in the claims.

For the above reasons the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 9 to delete the word "the" prior to "organisms" in their response to the rejection of this claim under 35 USC 112, 2<sup>nd</sup> paragraph. This amendment is not sufficient to overcome the rejection and raises new issues concerning what "organisms" are being referred to, i.e. are these organisms the uracil-auxotrophic

Art Unit: 1636

microorganisms referred to earlier in the claim? . Redrafting the claim to delete "organisms" and substituting "the microorganisms" would be remedial.

Any rejections not repeated in this Office Action are withdrawn.

Claims 1-2 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

Art Unit: 1636

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
June 8, 2003

DAVID GUZO  
PRIMARY EXAMINER

